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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/591,099 | 06/08/2007 | Takeshi Matsui | 082368-010000US | 4338 |
| 20350 | 7590 | 11/12/2008 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP | | | ALLEN, MARIANNE P | |
| TWO EMBARCADERO CENTER | | | | |
| EIGHTH FLOOR | | | ART UNIT | PAPER NUMBER |
| SAN FRANCISCO, CA 94111-3834 | | | 1647 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/12/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/591,099 | MATSUI ET AL. | |
| | Examiner | Art Unit | |
| | Marianne P. Allen | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 August 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 8 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4 and 8 is/are rejected.
 7) Claim(s) 5 and 6 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/1/07, 6/8/07</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 5-6 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only depend on claims in the alternative and cannot depend from another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-6 have not been further treated on the merits.

Election/Restrictions

Claims 7 and 9-20 have been cancelled. Applicant elected claims 1-6 and 8 and SEQ ID NOS: 7-8 without traverse and has amended the claims to reflect the elected invention.

Specification

The substitute specification filed 8/29/06 has been entered.

The specification does not reference the sequence identifiers that correspond to the sequences disclosed in Figure 2C and Figure 4A. See the figures and brief description of the figures. Correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not evidence the hand of man (e.g. reciting isolated, purified products) and encompass a product of nature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Valenzuela et al. (WO 99/55721).

Valenzuela et al. discloses SEQ ID NOS: 53 (1897 nucleotides) and 54 (479 amino acids). Probes and vectors are disclosed. SEQ ID NO: 53 of Valenzuela et al. has 92% identity to instant SEQ ID NO: 7 and SEQ ID NO: 54 of Valenzuela et al. has 96% identity to SEQ ID NO: 8. (See pages 85-88; pages 137-138; claims 62-63; and sequence alignment below.) Absent evidence to the contrary and in view of the high structural similarity, the polynucleotide and amino acid sequences of Valenzuela et al. would inherently possess the properties recited in claim 1 parts (c) and (d) and claim 2. Evidence that these properties are not possessed by the sequences of Valenzuela et al. will be viewed as evidence that the claims are not enabled for the breadth of the polynucleotides encompassed.

Sequence 1897 BP

Query Match 91.6%; Score 1816.2; DB 3; Length 1897;

Art Unit: 1647

Best Local Similarity 97.8%; Pred. No. 0;
 Matches 1855; Conservative 0; Mismatches 33; Indels 9; Gaps 1;

| | | | |
|----|-----|--|------|
| Qy | 85 | ACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGCAAGGAGGGAGCCCTGGTGGGAGGA | 144 |
| | | | |
| Db | 1 | ACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGCAAGGAGGGAGCCCTGGTGGGAGGA | 60 |
| | | | |
| Qy | 145 | AGACACTCTGGAGAGAGAGGGGCTGGCAGAGATGAAGTCCAGGGCCCTGGCCTGC | 204 |
| | | | |
| Db | 61 | AGACACTCTGGAGAGAGAGGGGCTGGCAGAGATGAAGTCCAGGGCCCTGGCCTGC | 120 |
| | | | |
| Qy | 205 | CTCCTGCTGGCCCTCTGCCTGGCAGTGGGAGGCAGGCCCTGCAGAGCGGAGAGGAA | 264 |
| | | | |
| Db | 121 | CTCCTGCTGGCCCTCTGCCTGGCAGTGGGAGGCAGGCCCTGCAGAGCGGAGAGGAA | 180 |
| | | | |
| Qy | 265 | AGCACTGGGACAATATTGGGGAGGCCCTGGACATGGCCTGGAGACGCCCTGAGCGAA | 324 |
| | | | |
| Db | 181 | AGCACTGGGACAATATTGGGGAGGCCCTGGACATGGCCTGGAGACGCCCTGAGCGAA | 240 |
| | | | |
| Qy | 325 | GGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGGCAGCTGGCTCAAAGTCAGTGAG | 384 |
| | | | |
| Db | 241 | GGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGGCAGCTGGCTCAAAGTCAGTGAG | 300 |
| | | | |
| Qy | 385 | GCCCTGGCAAGGGACCAGAGAACAGCTGGCACTGGAGTCAGGCAGGTCCAGGCTT | 444 |
| | | | |
| Db | 301 | GCCCTGGCAAGGGACCAGAGAACAGCTGGCACTGGAGTCAGGCAGGTCCAGGCTT | 360 |
| | | | |
| Qy | 445 | GGCGCAGCAGATGCTTGGCAACAGGGTCGGGAAGCAGCCATGCTCTGGAAACACT | 504 |
| | | | |
| Db | 361 | GGCGTAGCAGATGCTTGGCAACAGGGTCGGGAAGCAGCCATGCTCTGGAAACACT | 420 |
| | | | |
| Qy | 505 | GGGCACGAGATTGGCAGACAGGCAGAAGATGTCATTGACACGGCAGATGCTGTCCGC | 564 |
| | | | |
| Db | 421 | GGGCACGAGATTGGCAGACAGGCAGAAGATGTCATTGACACGGCAGATGCTGTCCGC | 480 |
| | | | |
| Qy | 565 | GGCTCCTGGCAGGGGTGCCTGCCACAATGGTCTGGAAACTCTGGAGGCCATGGC | 624 |
| | | | |
| Db | 481 | GGCTCCTGGCAGGGGTGCCTGCCACAATGGTCTGGAAACTCTGGAGGCCATGGC | 540 |
| | | | |
| Qy | 625 | ATCTTGGCTCTCAAGGTGGCCTTGGAGGCCAGGGCAGGGCAATCCTGGAGGTCTGGG | 684 |
| | | | |
| Db | 541 | ATCTTGGCTCTCAAGGTGGCCTTGGAGGCCAGGGCAGGGCAATCCTGGAGGTCTGGG | 600 |
| | | | |
| Qy | 685 | ACTCCGTGGTCCACGGATACCCGGAAACTCAGCAGGCAGCTTGGAAATGAATCCTCAG | 744 |
| | | | |
| Db | 601 | ACTCCGTGGTCCACGGATACCCGGAAACTCAGCAGGCAGCTTGGAAATGAATCCTCAG | 660 |
| | | | |
| Qy | 745 | GGAGCTCCCTGGGTCAAGGAGGCAATGGAGGCCACCAAACCTTGGACCAACACTCAG | 804 |
| | | | |
| Db | 661 | GGAGCTCCCTGGGTCAAGGAGGCAATGGAGGCCACCAAACCTTGGACCAACACTCAG | 720 |
| | | | |
| Qy | 805 | GGAGCTGTGGCCACGCCCTGGCATGGTCAGTGAGAGCCAGCAACCAGAAATGAAGGGTGC | 864 |
| | | | |
| Db | 721 | GGAGCTGTGGCCACGCCCTGGCATGGTCAGTGAGAGCCAGCAACCAGAAATGAAGGGTGC | 780 |
| | | | |
| Qy | 865 | ACGAATCCCCACCATCTGGCTCAGGTGGAGGCCAGCAACTCTGGGGAGGCAGCGGC | 924 |
| | | | |
| Db | 781 | ACGAATCCCCACCATCTGGCTCAGGTGGAGGCCAGCAACTCTGGGGAGGCAGCGGC | 840 |
| | | | |
| Qy | 925 | TCACAGTCGGCAGCAGTGGCAGTCAGCAATGGTACAACAACAATGGCAGCAGCAGT | 984 |
| | | | |
| Db | 841 | TCACAGTCGGCAGCAGTGGCAGTCAGCAATGGTACAACAACAATGGCAGCAGCAGT | 900 |
| | | | |
| Qy | 985 | GGTGGCAGCAGCAGTGGCAGCAGCAGTGGCAGCAGTGGCAGCAGTGGTGGCAGC | 1044 |
| | | | |
| Db | 901 | GGTGGCAGCAGCAGTGGCAGCAGCAGTGGCAGCAGTGGTGGCAGCAGTGGTGGCAGC | 960 |
| | | | |

Art Unit: 1647

Art Unit: 1647

Query Match 95.7%; Score 2462.5; DB 3; Length 479;
Best Local Similarity 96.0%; Pred. No. 5.9e-152;
Matches 460; Conservative 2; Mismatches 14; Indels 3; Gaps 2;

Qy 1 MKFQGPLACLLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEGVGKAIGKEAG 60
Db 1 MKFQGPLACLLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEGVGKAIGKEAG 60

Qy 61 GAAGSKVSEALGQGTREAVGTGVRQVPFGAADALGNRVGEAAHALGNTGHEIGRQAEDV 120
Db 61 GAAGSKVSEALGQGTREAVGTGVRQVPFGVADALGNRVGEAAHALGNTGHEIGRQAEDV 120

Qy 121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSQGGLGGQQGQNPGLTPWVHGPNS 180
Db 121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSQGGLGGQQGQNPGLTPWVHGPNS 180

Qy 181 AGSFGMNPQGAPWGQGGNGPPNFTNTQGAVAQPGYGSVRASNQNEGCTNPPPSGSGGG 240
Db 181 AGSFGMNPQGAPWGQGGNGPPNFTNTQGAVAQPGYGSVRASNQNEGCTNPPPSGSGGG 240

Qy 241 SSNSGGGSGSQSGSSGSGNSGNDNNNGSSSGSSGGSSGGSSGSSGNSGGSRGDS 300
Db 241 SSNSGGGSGSQSGSSGSGNSGNDNNNGSSSGSSGGSSGGSSGSSGNSGGSRGDS 300

Qy 301 GSESSWGSSTGSSGNHGGGGNGHKPGCE-KPGNEARGSGESGIQ--NSETSPGMNF 357
Db 301 GSESSWGSSTGSSGNHGGGGNGHKPGGQGSSWGSGGDAVGVNTVNSETSPGMNF 360

Qy 358 DTFWKNFKSKLGFINWDAINKNQVPPPSTRALLYFSRLWEDFKQNTPFLNWKAIIEGADA 417
Db 361 DTFWKNFKSKLGFINWDAINKNQVPPPSTRALLYFSRLWEDFKQNTPFLNWKAIIEGADA 420

Qy 418 SSLQKRAGRADQNYYNQHAYPTAYGGKYSVTKPAKGGVSPSSASRVQPGLLQWVKFW 476
Db 421 SSLQKRAGRADQNYYNQHAYPTAYGGKYSVTKPAKGGVSPSSASRVQPGLLQWVKFW 479

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsui et al. (Genomics, August 2004).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Matsui et al. discloses the gene and amino acid sequences corresponding to instant SEQ ID NOS: 7 and 8. See at least page 384 which discloses the sequences were deposited with Genbank and Figure 2.

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Claims 1-4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Song et al. (U.S. Patent No 7,326,687).

Song et al. discloses SEQ ID NOS: 2 (2097 nucleotides) and 3 (555 amino acids). Vectors are disclosed. SEQ ID NO: 2 of Song et al. has 80% identity to instant SEQ ID NO: 7 and SEQ ID NO: 3 of Song et al. has 97% identity to SEQ ID NO: 8. (See sequence listing, claims, and sequence alignment below.) Absent evidence to the contrary and in view of the high structural similarity, the polynucleotide and amino acid sequences of Song et al. would inherently possess the properties recited in claim 1 parts (c) and (d) and claim 2. Evidence that these properties are not possessed by the sequences of Song et al. will be viewed as evidence that the claims are not enabled for the breadth of the polynucleotides encompassed.

Query Match 80.4%; Score 1593; DB 6; Length 2097;
Best Local Similarity 88.7%; Pred. No. 0;
Matches 1860; Conservative 0; Mismatches 0; Indels 237; Gaps 3;

| | | | |
|----|-----|--|-----|
| Qy | 78 | GAGGAGGACAGAGGGAGGCACAGAGACGCAGAGCAAGGGCGCAAGGAGGAGACCCCTGGT | 137 |
| | | | |
| Db | 1 | GAGGAGGACAGAGGGAGGCACAGAGACGCAGAGCAAGGGCGCAAGGAGGAGACCCCTGGT | 60 |
| Qy | 138 | GGGAGGAAGACACTCTGGAGAGAGAGGGGCTGGCAGAGATGAAGTTCCAGGGCCCCCT | 197 |
| | | | |
| Db | 61 | GGGAGGAAGACACTCTGGAGAGAGAGGGGCTGGCAGAGATGAAGTTCCAGGGCCCCCT | 120 |
| Qy | 198 | GGCCTGCCCTCGTGGCCCTCTGCCCTGGGCACTGGGGAGGTGGCTGGCCCCCTGCAGAGCGG | 257 |
| | | | |
| Db | 121 | GGCCTGCCCTCGTGGCCCTCTGCCCTGGGCACTGGGGAGGTGGCTGGCCCCCTGCAGAGCGG | 180 |
| Qy | 258 | AGAGGAAAGCACTGGGACAATATTGGGGAGGCCATTGGCACATGGCTGGGAGACGCCCT | 317 |
| | | | |
| Db | 181 | AGAGGAAAGCACTGGGACAATATTGGGGAGGCCATTGGCACATGGCTGGGAGACGCCCT | 240 |
| Qy | 318 | GAGCGAAGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGGCAGCTGGCTCTAAAGT | 377 |
| | | | |
| Db | 241 | GAGCGAAGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGGCAGCTGGCTCTAAAGT | 300 |
| Qy | 378 | CAGTGAGGCCATTGGCCAAGGGCAGAGAAGCAGTTGGCACTGGAGTCAGGCAGGTTCC | 437 |
| | | | |
| Db | 301 | CAGTGAGGCCATTGGCCAAGGGCAGAGAAGCAGTTGGCACTGGAGTCAGGCAGGTTCC | 360 |
| Qy | 438 | AGGCTTTGGCGCAGCAGATGCTTGGCAACAGGGTGGGGAAAGCAGCCATGCTCTGGG | 497 |
| | | | |
| Db | 361 | AGGCTTTGGCGCAGCAGATGCTTGGCAACAGGGTGGGGAAAGCAGCCATGCTCTGGG | 420 |
| Qy | 498 | AAACACTGGGCACGAGATTGGCAGACAGGCAGAAAGATGTCATTGACACGGAGCAGATGC | 557 |
| | | | |
| Db | 421 | AAACACTGGGCACGAGATTGGCAGACAGGCAGAAAGATGTCATTGACACGGAGCAGATGC | 480 |

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Qy 558 TGTCCGGGCTCCTGGCAGGGGTGCCTGGCCACAATGGTCTGGAAACTCTGGAGG 617
 |||||||
 Db 481 TGTCCGGGCTCCTGGCAGGGGTGCCTGGCCACAATGGTCTGGAAACTCTGGAGG 540
 |||||||
 Qy 618 CCATGGCATTTGGCTCTCAAGGTGGCCTGGAGGCCAGGGCAATCCTGGAGG 677
 |||||||
 Db 541 CCATGGCATTTGGCTCTCAAGGTGGCCTGGAGGCCAGGGCAATCCTGGAGG 600
 |||||||
 Qy 678 TCTGGGACTCCGTGGTCCACGGATACCCCGAAACTCAGCAGGCAGCTTGAATGAA 737
 |||||||
 Db 601 TCTGGGACTCCGTGGTCCACGGATACCCCGAAACTCAGCAGGCAGCTTGAATGAA 660
 |||||||
 Qy 738 TCCTCAGGGAGCTCCCTGGGTCAAGGAGGCAATGGAGGGCACCAAACCTTGGACCAA 797
 |||||||
 Db 661 TCCTCAGGGAGCTCCCTGGGTCAAGGAGGCAATGGAGGGCACCAAACCTTGGACCAA 720
 |||||||
 Qy 798 CACTCAGGGAGCTGTGGCCCAGCCTGGCTATGGTCAGTGAGAGGCCAGAACAGAATGA 857
 |||||||
 Db 721 CACTCAGGGAGCTGTGGCCCAGCCTGGCTATGGTCAGTGAGAGGCCAGAACAGAATGA 780
 |||||||
 Qy 858 AGGGTGCACGAATCCCCACCATCTGGCTCAGGTGGAGGCTCCAGCAACTCTGGGGAGG 917
 |||||||
 Db 781 AGGGTGCACGAATCCCCACCATCTGGCTCAGGTGGAGGCTCCAGCAACTCTGGGGAGG 840
 |||||||
 Qy 918 CAGCGGCTCACAGTCGGCAGCAGTCAGTGGCAGCAATGGTACAACACAATGGCAG 977
 |||||||
 Db 841 CAGCGGCTCACAGTCGGCAGCAGTCAGTGGCAGCAATGGTACAACACAATGGCAG 900
 |||||||
 Qy 978 CAGCAGTGGTGGCAGCAGCAGTCAGTGGCAGCAGCAGTGGCGCAGCAGTGGCGCAGCAGTGG 1037
 |||||||
 Db 901 CAGCAGTGGTGGCAGCAGCAGTCAGTGGCAGCAGCAGTCAGTGGCGCAGCAGTGGCGCAGCAGTGG 960
 |||||||
 Qy 1038 TGGCAGCAGTGGCAACAGTGGTGGCAGCAGAGGTGACAGCAGCAGTGGCCTCTG--- 1094
 |||||||
 Db 961 TGGCAGCAGTGGCAACAGTGGTGGCAGCAGAGGTGACAGCAGCAGTGGCCTCTGGGG 1020
 |||||||
 Qy 1095 -----GGGATCCAGCACCGGCTC 1112
 |||||||
 Db 1021 CAGTTCTGGGAATGGTGACCAAGGCAGCTACGGCCGCTCCCAGGGATCCAGCACCGGCTC 1080
 |||||||
 Qy 1113 CTCCCTCGGCAACCACGGTGGAGCGGGAGGAAATGGACATAAACCGGGTGTAAAA 1172
 |||||||
 Db 1081 CTCCCTCGGCAACCACGGTGGAGCGGGAGGAAATGGACATAAACCGGGTGTAAAA 1140
 |||||||
 Qy 1173 GCCAGGGAATGAAGCCCAGGGAGCGGGAAATCTGGG----- 1209
 |||||||
 Db 1141 GCCAGGGAATGAAGCCCAGGGAGCGGGAAATCTGGGATTCAAGGCTTCAGAGGACAGGG 1200
 |||||||
 Qy 1210 ----- 1209
 |||||||
 Db 1201 AGTTTCAGCAACATGAGGAAATAAGCAAAGAGGGCAATCGCCTCCTGGAGGCTCTGG 1260
 |||||||
 Qy 1210 ----- 1209
 |||||||
 Db 1261 AGACAATTATCGGGGCAAGGGTCAGCTGGGAGCAGGAGGTGACGCTGTTGGTGG 1320
 |||||||
 Qy 1210 -----ATTCAGAACTCTGAGACGTCTCCTGGATGTTAACTTGCACACTTCTGGAA 1262
 |||||||
 Db 1321 AGTCAATATTCAAGACTCTGAGACGTCTCCTGGATGTTAACTTGCACACTTCTGGAA 1380
 |||||||
 Qy 1263 GAATTAAATCCAAGCTGGGTTCATCAACTGGGATGCCATAAACAGAACCGAGGTCCC 1322
 |||||||
 Db 1381 GAATTAAATCCAAGCTGGGTTCATCAACTGGGATGCCATAAACAGAACCGAGGTCCC 1440
 |||||||
 Qy 1323 GCCCCCAGCACCCGAGCCCTCCTACTTCAGCCGACTCTGGAGGATTCAAACAGAA 1382
 |||||||

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Db 1441 GCCCCCCAGCACCCGAGCCCTCCTACTTCAGCGACTCTGGGAGGATTCAACAGAA 1500
 Qy 1383 CACTCCTTCCTCAACTGGAAAGCAATTATTGAGGGTCCGGACCGCTCATCACTGCAGAA 1442
 |||||||
 Db 1501 CACTCCTTCCTCAACTGGAAAGCAATTATTGAGGGTCCGGACCGCTCATCACTGCAGAA 1560
 |||||||
 Qy 1443 ACGTGCAGGCAGAGCCGATCAGCCGGTGCAGGATGGCAGGAGGTGGCAGCTGTAACCTC 1462
 |||||||
 Db 1561 ACGTGCAGGCAGAGCCGATCAGCCGGTGCAGGATGGCAGGAGGTGGCAGCTGTAACCTC 1620
 |||||||
 Qy 1463 --AGAACTACAATTACAACCAGCATGCGTATCCCCTGCCTATGGTGGGAAGTACTCAGT 1520
 |||||||
 Db 1621 CAAGAACTACAATTACAACCAGCATGCGTATCCCCTGCCTATGGTGGGAAGTACTCAGT 1680
 |||||||
 Qy 1521 CAAGACCCCTGCAAAGGGGGAGTCTCACCTTCTCGGCTCCCGGGTGCAACCTGG 1580
 |||||||
 Db 1681 CAAGACCCCTGCAAAGGGGGAGTCTCACCTTCTCGGCTCCCGGGTGCAACCTGG 1740
 |||||||
 Qy 1581 CCTGCTGCAGTGGGTGAAGTTGGTAGGCAATTCTTGCAACCACCCAGGCCCCGA 1640
 |||||||
 Db 1741 CCTGCTGCAGTGGGTGAAGTTGGTAGGCAATTCTTGCAACCACCCAGGCCCCGA 1800
 |||||||
 Qy 1641 AAAGCACTGGTCGTCAAGGGAGCTCCCTCCCTGGCCCCCAGCCTGTGCCAGCCCTGGCCC 1700
 |||||||
 Db 1801 AAAGCACTGGTCGTCAAGGGAGCTCCCTCCCTGGCCCCCAGCCTGTGCCAGCCCTGGCCC 1860
 |||||||
 Qy 1701 GGCTGCCACACCTCTGTTCTAGGCTGGGGACCCAGCTGTCTCTCCTGTTCTCCC 1760
 |||||||
 Db 1861 GGCTGCCACACCTCTGTTCTAGGCTGGGGACCCAGCTGTCTCTCCTGTTCTCCC 1920
 |||||||
 Qy 1761 ACTGCACTGTGGTCTCAGTGGGACCAGCCTCGTCACATAACACCAGCATTTCTGTA 1820
 |||||||
 Db 1921 ACTGCACTGTGGTCTCAGTGGGACCAGCCTCGTCACATAACACCAGCATTTCTGTA 1980
 |||||||
 Qy 1821 CCTCCTCCCTTGGTACACTGAAGTCACTGTGACAGTTCTCAGGAAGGAGGAGCTCCT 1880
 |||||||
 Db 1981 CCTCCTCCCTTGGTACACTGAAGTCACTGTGACAGTTCTCAGGAAGGAGGAGCTCCT 2040
 |||||||
 Qy 1881 ACTTTGAGTTCTGTGGAAATAAACATGAATCTGTTCCCTAAAAAAAAAAA 1937
 |||||||
 Db 2041 ACTTTGAGTTCTGTGGAAATAAACATGAATCTGTTCCCTAAAAAAAAAAA 2097

Query Match 97.3%; Score 2503.5; DB 3; Length 555;
 Best Local Similarity 85.8%; Pred. No. 1.2e-171;
 Matches 476; Conservative 0; Mismatches 0; Indels 79; Gaps 3;

Qy 1 MKFQGPLACLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEGVGKAIGKEAG 60
 |||||||
 Db 1 MKFQGPLACLLALCLGSGEAGPLQSGEESTGTNIGEALGHGLGDALSEGVGKAIGKEAG 60
 |||||||
 Qy 61 GAAGSKVSEALQQTREAVGTGVRQVPFGAADALGNRVGEAAHALGNTGHEIGRQAEDV 120
 |||||||
 Db 61 GAAGSKVSEALQQTREAVGTGVRQVPFGAADALGNRVGEAAHALGNTGHEIGRQAEDV 120
 |||||||
 Qy 121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSQGGLGGQGQGNPGGLGTPWVHGPNS 180
 |||||||
 Db 121 IRHGADAVRGSWQGVPGHNGAWETSGGHGIFGSQGGLGGQGQGNPGGLGTPWVHGPNS 180
 |||||||
 Qy 181 AGSFGMNPQGAPWGQGGNGPPNFTNTQGAVAQPGYGSVRASRNQNEGCTNPPSGSGGG 240
 |||||||
 Db 181 AGSFGMNPQGAPWGQGGNGPPNFTNTQGAVAQPGYGSVRASRNQNEGCTNPPSGSGGG 240
 |||||||
 Qy 241 SSNSGGSGSQSGSSGSGSNGDNNNGSSSSGSSGGSSGGSSGSSGNSGSRGDS 300
 |||||||
 Db 241 SSNSGGSGSQSGSSGSGSNGDNNNGSSSSGSSGGSSGSSGNSGSRGDS 300

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| | | |
|----|---|-----|
| Qy | 301 GSESSW-----GSSTGSSSGNHGGGGNGHPGCEKPGNEARGSGESG- | 344 |
| | | |
| Db | 301 GSESSWGSSGNGDQGSYGRSQGSSTGSSGNHGGGGNGHPGCEKPGNEARGSGESGI | 360 |
| Qy | 345 -----IQNSETSPGMF | 355 |
| | | |
| Db | 361 QGFRGQGVSSNMREISKEGNRLGGSGDNYRGQQSSWGSGGDAVGGVNIQNSETSPGMF | 420 |
| Qy | 356 NFDTFWKNFKSKLGFINWDAINKNQVPPPSTRALLYFSRLWEDFKQNTPFLNKAIIEGA | 415 |
| | | |
| Db | 421 NFDTFWKNFKSKLGFINWDAINKNQVPPPSTRALLYFSRLWEDFKQNTPFLNKAIIEGA | 480 |
| Qy | 416 DASSLQKRAGRADQ-----NYNQNQHAYPTAYGGKYSVKTPAKGGVSPSSS | 461 |
| | | |
| Db | 481 DASSLQKRAGRADQPGAGWQEVAVTSKNQHAYPTAYGGKYSVKTPAKGGVSPSSS | 540 |
| Qy | 462 ASRVQPGLLQWVKFW | 476 |
| | | |
| Db | 541 ASRVQPGLLQWVKFW | 555 |

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al. (PNAS, 2002) in view of Genbank Accession No. BC035311 (9/20/02 and 10/12/04 entry revision).

Strausberg et al. discloses a sequence that is identical to instant SEQ ID NO: 7. This sequence was deposited with Genbank. See abstract and sequence alignment of instant SEQ ID NO: 7 with the sequence of BC035311 below. The 10/12/2004 revision of Genbank Accession No. BC035311 identifies this sequence as encoding a dermokine and provides the translated sequence corresponding to SEQ ID NO: 8. The nucleotide sequence in BC035311 was available as of 9/20/02. Applicant is advised that Genbank Accession No. BC035311 references Genbank Accession No. AAH35311. AAH35311 provides the amino acid sequence and was available as of 10/12/04.

Applicant referenced BC035311 in the specification at page 12, line 16.

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Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Query Match 100.0%; Score 1982; DB 5; Length 1982;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 1982; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 TCTGAGAAGCCCAGGCAGTTGAGGACAGGAGAGAGAAGGCTGCAGACCCAGAGGGAGGGA 60
Db 1 TCTGAGAAGCCCAGGCAGTTGAGGACAGGAGAGAGAAGGCTGCAGACCCAGAGGGAGGGA 60

Qy 61 GGACAGGGAGTCGGAAGGAGGGACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGGC 120
Db 61 GGACAGGGAGTCGGAAGGAGGGACAGAGGAGGGCACAGAGACGCAGAGCAAGGGCGGC 120

Qy 121 AAGGAGGGAGACCCCTGGTGGGAGGAAGACACTCTGGAGAGAGAGAGGGGCTGGCAGAGATG 180
Db 121 AAGGAGGGAGACCCCTGGTGGGAGGAAGACACTCTGGAGAGAGAGAGGGGCTGGCAGAGATG 180

Qy 181 AAGTTCCAGGGGCCCTGGCCTGCCCTGCCTGGCCCTCTGCCCTGGCAGTGGGAGGCT 240
Db 181 AAGTTCCAGGGGCCCTGGCCTGCCCTGCCTGGCCCTTGCCCTGGCAGTGGGAGGCT 240

Qy 241 GGCCCCCTGCAGAGCGGAGAGGAAAGCACTGGGACAATATTGGGAGGCCCTTGGACAT 300
Db 241 GGCCCCCTGCAGAGCGGAGAGGAAAGCACTGGGACAATATTGGGAGGCCCTTGGACAT 300

Qy 301 GGCCTGGAGACGCCCTGAGCGAAGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGG 360
Db 301 GGCCTGGAGACGCCCTGAGCGAAGGGTGGGAAAGGCCATTGGCAAAGAGGCCGGAGGG 360

Qy 361 GCAGCTGGCTCTAAAGTCAGTGAGGCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACT 420
Db 361 GCAGCTGGCTCTAAAGTCAGTGAGGCCCTTGGCCAAGGGACCAGAGAAGCAGTTGGCACT 420

Qy 421 GGAGTCAGGCAGGTTCCAGGCTTGGCGCAGCAGATGCTTGGCAACAGGGTCGGGAA 480
Db 421 GGAGTCAGGCAGGTTCCAGGCTTGGCGCAGCAGATGCTTGGCAACAGGGTCGGGAA 480

Qy 481 GCAGCCCATGCTCTGGAAACACTGGCAGAGATTGGCAGACAGGCAGAAGATGTCATT 540
Db 481 GCAGCCCATGCTCTGGAAACACTGGCAGAGATTGGCAGACAGGCAGAAGATGTCATT 540

Qy 541 CGACACGGAGCAGATGCTGTCCGGCTCCTGCCAGGGGGTGCCTGGCCACAATGGTGCT 600
Db 541 CGACACGGAGCAGATGCTGTCCGGCTCCTGCCAGGGGGTGCCTGGCCACAATGGTGCT 600

Qy 601 TGGGAAACTCTGGAGGCCATGGCATTTGGCTCTCAAGGTGGCCTGGAGGCCAGGGC 660
Db 601 TGGGAAACTCTGGAGGCCATGGCATTTGGCTCTCAAGGTGGCCTGGAGGCCAGGGC 660

Qy 661 CAGGGCAATCCTGGAGGTCTGGGACTCCGTGGTCCACGGATAACCCGGAAACTCAGCA 720
Db 661 CAGGGCAATCCTGGAGGTCTGGGACTCCGTGGTCCACGGATAACCCGGAAACTCAGCA 720

Qy 721 GGCAGCTTGGATGAATCCTCAGGGAGCTCCCTGGGTCAAGGAGGCAATGGAGGCCA 780
Db 721 GGCAGCTTGGATGAATCCTCAGGGAGCTCCCTGGGTCAAGGAGGCAATGGAGGCCA 780

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Db 721 GGCAGCTTGGAAATGAATCCTCAGGGAGCTCCCTGGGTCAAGGAGGCAATGGAGGGCCA 780
 Qy 781 CCAAACCTTGGGACCAACACTCAGGGAGCTGTGGCCAGCCTGGCTATGGTCAGTGAGA 840
 |||||||
 Db 781 CCAAACCTTGGGACCAACACTCAGGGAGCTGTGGCCAGCCTGGCTATGGTCAGTGAGA 840
 Qy 841 GCCAGCAACCAGAACATGAAGGGTGCACGAATCCCCACCACATCTGGCTCAGGTGGAGGCTCC 900
 |||||||
 Db 841 GCCAGCAACCAGAACATGAAGGGTGCACGAATCCCCACCACATCTGGCTCAGGTGGAGGCTCC 900
 Qy 901 AGCAACTCTGGGGAGGCAGCGGTCACAGTCGGCAGCAGTGGCAGTGGCAGCAATGGT 960
 |||||||
 Db 901 AGCAACTCTGGGGAGGCAGCGGTCACAGTCGGCAGCAGTGGCAGTGGCAGCAATGGT 960
 Qy 961 GACAACAACAATGGCAGCAGCAGTGGTGGCAGCAGCAGCAGTGGCAGCAGCAGTGGCGCAGC 1020
 |||||||
 Db 961 GACAACAACAATGGCAGCAGCAGTGGTGGCAGCAGCAGTGGCAGCAGCAGTGGCGCAGC 1020
 Qy 1021 AGTGGCGGCAGCAGTGGTGGCAGCAGTGGCAACAGTGGTGGCAGCAGGAGGTGACAGCGGC 1080
 |||||||
 Db 1021 AGTGGCGGCAGCAGTGGTGGCAGCAGTGGCAACAGTGGTGGCAGCAGGAGGTGACAGCGGC 1080
 Qy 1081 AGTAGTCCTCCTGGGATCCAGCACCGGCTCCCTCCGGCAACCACGGTGGAGCGGC 1140
 |||||||
 Db 1081 AGTAGTCCTCCTGGGATCCAGCACCGGCTCCCTCCGGCAACCACGGTGGAGCGGC 1140
 Qy 1141 GGAGGAAATGGACATAAACCCGGGTGTGAAAAGCCAGGGAAATGAAGCCCGGGAGCGGG 1200
 |||||||
 Db 1141 GGAGGAAATGGACATAAACCCGGGTGTGAAAAGCCAGGGAAATGAAGCCCGGGAGCGGG 1200
 Qy 1201 GAATCTGGGATTCAAGAACTCTGAGACGTCTCTGGGATGTTAACTTGACACTTCTGG 1260
 |||||||
 Db 1201 GAATCTGGGATTCAAGAACTCTGAGACGTCTCTGGGATGTTAACTTGACACTTCTGG 1260
 Qy 1261 AAGAATTAAATCCAAGCTGGTTCATCAACTGGGATGCCATAAACAAAGAACCAAGGTC 1320
 |||||||
 Db 1261 AAGAATTAAATCCAAGCTGGTTCATCAACTGGGATGCCATAAACAAAGAACCAAGGTC 1320
 Qy 1321 CGCCCCCCCAGCACCGAGCCCTCTACTTCAGCCACTCTGGGAGGATTCAAACAG 1380
 |||||||
 Db 1321 CGCCCCCCCAGCACCGAGCCCTCTACTTCAGCCACTCTGGGAGGATTCAAACAG 1380
 Qy 1381 AACACTCCTTCCTCAACTGGAAAGCAATTATTGAGGGTGCAGCGTCATCACTGCAG 1440
 |||||||
 Db 1381 AACACTCCTTCCTCAACTGGAAAGCAATTATTGAGGGTGCAGCGTCATCACTGCAG 1440
 Qy 1441 AAACGTGCAGGCAGAGCCGATCAGAACTACAATTACAACCAGCATGCGTATCCCACTGCC 1500
 |||||||
 Db 1441 AAACGTGCAGGCAGAGCCGATCAGAACTACAATTACAACCAGCATGCGTATCCCACTGCC 1500
 Qy 1501 TATGGTGGGAAGTACTCAGTCAAGACCCCTGCAAAGGGGGAGTCTCACCTTCTTCCTCG 1560
 |||||||
 Db 1501 TATGGTGGGAAGTACTCAGTCAAGACCCCTGCAAAGGGGGAGTCTCACCTTCTTCCTCG 1560
 Qy 1561 GCTTCCCGGGTGCACCTGGCTGCTGCAGTGGTGAAGTTGGTAGGCAATTCTTG 1620
 |||||||
 Db 1561 GCTTCCCGGGTGCACCTGGCTGCTGCAGTGGTGAAGTTGGTAGGCAATTCTTG 1620
 Qy 1621 AACCAACCCAGGAGGCCCCGAAAGCACTGGTCAGGGAGCTCCTCCCCCTGGCCCCCA 1680
 |||||||
 Db 1621 AACCAACCCAGGAGGCCCCGAAAGCACTGGTCAGGGAGCTCCTCCCCCTGGCCCCCA 1680
 Qy 1681 GCCTGTGCCAGCCCTGGCCGGCTGCCACACCTGTTCTAGGCTGGGACCCAGCTT 1740
 |||||||
 Db 1681 GCCTGTGCCAGCCCTGGCCGGCTGCCACACCTGTTCTAGGCTGGGACCCAGCTT 1740
 Qy 1741 GTCTCTCCTGTTCTCCACTGCAGTGGTCTCAGTGGCACCAGCCTCGTCACA 1800

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Db      ||||||| 1741 GTCTCTCCTGTTCTCCACTGCACTGTGGTGCCTCAGTGGCCACCAGCCTCGTCACA 1800
Qy      1801 TACACCAGCATTTCTGTACCTCCCTTGGTACCTGAAGTCACTGTGACAGTTCT 1860
Db      1801 TACACCAGCATTTCTGTACCTCCCTTGGTACCTGAAGTCACTGTGACAGTTCT 1860
Qy      1861 CCAGGAAGGAGGAGCTCCTACTTTGAGTTCTGTGGAAATAAACATGAATCTTGT 1920
Db      1861 CCAGGAAGGAGGAGCTCCTACTTTGAGTTCTGTGGAAATAAACATGAATCTTGT 1920
Qy      1921 TTCCCTAaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa 1980
Db      1921 TTCCCTAaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa 1980
Qy      1981 AA 1982
Db      1981 AA 1982

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2-4 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 2 is directed to a gene involved in keratinocyte differentiation or proliferation, wherein the gene encodes a secreted protein. The specification does not disclose the nucleotide sequence for any gene. The gene sequence including introns and exons is not disclosed. The specification does not disclose nor contemplate genes corresponding to claim 1. Claim 1, part (a), is directed to degenerate sequences. Claim 1, part (b), is directed to coding regions alone. Claim 1, parts (c) and (d), are directed to non-naturally occurring sequences. None of these would have a naturally occurring or corresponding gene.

Claims 3-4 and 8 as they depend from claim 2 are not enabled for the same reason.

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claim 1, parts (a) and (b), does not reasonably provide enablement for any other sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1, parts (c) and (d), are directed to polynucleotides encoding polypeptides with particular properties. The specification does not demonstrate that SEQ ID NO: 7, encoding the polypeptide of SEQ ID NO: 8, has these properties. The polypeptide of SEQ ID NO: 8 is never administered to keratinocytes where these effects are seen. The polynucleotide of SEQ ID NO: 7 is never administered to keratinocytes where these effects are seen. The presence of SEQ ID NO: 7 in a Northern blot does not establish that this sequence is responsible for any particular activity. One of ordinary skill in the art would not have attributed this activity to SEQ ID NO: 7 without further experimentation and characterization. This is not present in the instant specification. Likewise, the specification does not disclose variant sequences (having substitutions, deletions, insertions, and/or additions or that have unspecified sequences that hybridize) that possess these properties. Those regions or amino acids responsible for this activity are not disclosed in the specification. As such, one of ordinary skill in the art would have no direction or guidance as to those polynucleotides to produce that would encode polypeptides having the required properties.

Claims 3-4 as they depend from claim 1 are not enabled for the same reason.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa